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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,377	03/16/2001	Matthew M. Graf	PA-5239-RFB	8787

9896 7590 05/23/2003

COOK GROUP PATENT OFFICE
P.O. BOX 2269
BLOOMINGTON, IN 47402

EXAMINER

HOOK, JAMES F

ART UNIT	PAPER NUMBER
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3752

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DATE MAILED: 05/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory ActionApplication No.
09/810,377Applicant(s)
Graf et al.Examiner
James F. HookArt Unit
3752

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED May 8, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attached
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: none
- Claim(s) objected to: none
- Claim(s) rejected: 1, 2, 4-6, and 10-16
- Claim(s) withdrawn from consideration: none
8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

JAMES F. HOOK
PRIMARY EXAMINER
ART UNIT 3752

Art Unit: 3752

Response to Arguments

1. Applicant's arguments filed May 8, 2003 have been fully considered but they are not persuasive. With regards to the arguments set forth in regards to various aspects of applicants article including how its made and various other features resulting from structure that is not set forth as limitations in the claims, such are not considered valid arguments when only claimed structure can be considered at this time. Therefore most of the arguments set forth in pages 2 and 3 of the response mentioned above deal with various structure which relates more to the method the article was made than the actual claim structure which is a sheath formed of a body with less radiopaque material than a tip portion which is made of FEP. In general the arguments seem to set forth a sheath that is formed with specific benefits from using the same material for the sheath as the tip, such is not set forth in the claims until dependent claim 15 which recites the same material, FEP and that the shaft is made from that material, and the arguments seem to suggest that unexpected results were found by using the same material for the shaft as the tip section. It is the examiners position that the base reference to Parker sets forth a sheath layer that has a shaft portion and tip portion made of the same material, polyamide or nylon, and that the tip section is more heavily loaded than the shaft portion. It is considered that the same results would be achieved by Parker using the same material for the shaft and tip as applicant has achieved without any differing structure claimed. Therefore, the only structure that Parker lacks is using FEP as the material used to make the tip and shaft portion which Parker has already set forth is

Art Unit: 3752

made of the same materials. The modifying reference to Jansen is used to modify the materials used to form the shaft and tip of Parker by teaching that for uses such as catheters, sleeves can be formed of various materials of which polyamides, or nylons, are equivalent to the use of FEP, and fluoropolymers are known to have desirable aspects over nylons, one being to form a more lubricated surface based on the known properties of the materials. Therefore, it is considered obvious that one skilled in the art could modify the sleeve in Parker which utilizes polyamides for the shaft and tip portions and substitute therefore an FEP material as suggested by Jansen. There appear to be no arguments directed toward this combination based on how the combination is formulated so there is no convincing evidence that such is in error at this time. With respect to the patent to Coneys, such is not relied upon for rejecting the claims but is merely provided as evidence that applicant has not achieved unexpected results of loading FEP with high amounts of radiopaque materials. Applicant has repeatedly used the term "surprisingly" in discussing the results achieved by applicant's article, which is being interpreted as an attempt to imply unexpected results. However, Parker itself suggests expected positive results of using the same material for the tip as is used for the shaft, which also inherently would give a better connection than using different materials, and therefore there are no unexpected results of this feature of applicants article. FEP is a known material used for applications in catheters, so it's not considered unexpected to use FEP in place of the polyamides used for the shaft and tip in Parker as suggested by Jansen. Any argument directed toward unexpected results of using high loadings of radiopaque materials in FEP is not persuasive either based on the evidence provided by

Art Unit: 3752

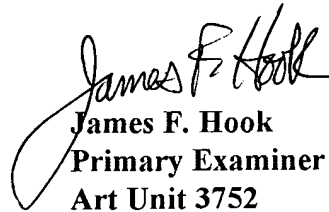
Coneys. Since Coneys is not being relied upon for anything other than evidence and not being used as a modifying reference, further discussion of this reference will be kept brief. Coneys sets forth in column 3, lines 35-43 that the blended mixture of radiopaque material and plastic forms layer 14 and that such is then placed between layers 12 of pure plastic material to form the catheter. It then sets forth in column 3, lines 50-55 that this blended mixture of radiopaque material defining layer 14 includes between 20-30% FEP with the "remaining seventy percent to eighty percent being one of the radiopaque materials" which shows that the layer 14 is made up of FEP that is highly loaded with radiopaque material and therefore one would not consider this an unexpected result to achieve FEP with high loadings of radiopaque materials based on the evidence provided by Coneys. The part of Coneys referring to the 12-25% appears to be in error when referring to reference number 14 in column 3, lines 58-65, when such is clearly talking about the entire catheter tube including layers 12 when talking of the overall amount present of radiopaque material, in that any other interpretation would be contrary to the clear statement set forth in lines 50-55 that the layer 14 is made of the mixture including 70-80% radiopaque material which clearly teaches that high loadings of radiopaque materials are known in FEP. Coney's is not used in any other way other than as evidence that there is no case of unexpected results. It is considered that the teachings of Parker to use the same material for the tip and shaft of a catheter and utilizing polyamides can then be modified by Jansen that teaches FEP can be used in place of polyamides for catheters. It is not the examiners position that Jansen provide support for forming the tip of FEP, such is provided by Parker that teaches that the tip and shaft should be made of the

Art Unit: 3752

same material. Therefore, Jansen is teaching the equivalence of using FEP in place of polyamides in catheters, and that based upon this teaching that the tip in Parker can be made of FEP as well as the shaft to provide a shaft and tip made of the same material.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Hook whose telephone number is (703) 308-2913.

J. Hook
May 21, 2003


James F. Hook
Primary Examiner
Art Unit 3752